REMARKS

The specification has been amended to update the Related Applications paragraph and to correct certain informalities.

Claims 25-28 and 50-59 have been canceled without prejudice. Claims 60-96 are pending.

Claims 60, 61, 65-66, 73, 74, 78-79, 86 and 90-91 have been amended to recite "TECK" and "TECK-induced response." Support for this amendment can be found, for example, at page 11, lines 2-4 and at page 14, lines 9-13.

Claims 60 and 86 have been amended to recite that the GPR-9-6 "comprises an amino acid sequence that is at least about 90% similar to the amino acid sequence of SEQ ID NO:2." Support for these amendments is found, for example, at page 20, lines 6-10.

Claims 61 and 74 have been amended to recite "chemotaxis, Ca^{2+} flux, GDP/GTP exchange by GPR-9-6 associated G proteins, cellular proliferation, cellular migration, secretion, exocytosis, degranulation, inflammatory mediator release or respiratory burst." Support for this amendment is found, for example, at page 14, lines 14-23 and at page 25, lines 5-9. Claim 86 has been amended to recite "chemotaxis" and "Ca^{2+} flux" as cellular responses. Support for these amendments are found throughout the Specification and, in particular, at page 14, lines 14-17.

Claims 60, 73 and 86 have been amended to recite "GPR-9-6" for consistent terminology throughout the claims. Support for this amendment is found throughout the Specification, for example, at page 11, lines 5-8.

Claims 67 and 68 have been amended to delete "mammalian" and reference to "functional variant."

Claim 73 has been amended to recite that the GPR-9-6 "is recognized by mAb 3C3 (ATCC HB-12653)." Support for this amendment is found, for example, at page 14, line 27 through page 15, line 21.

The amended claims find support in the application as originally filed. Therefore, this Amendment does not add new matter. Further remarks are set forth below with reference to the numbered paragraphs of the Office Action.

Paragraph 4. Priority

The Related Applications Paragraph has been updated to indicate that U.S. Application No. 09/266,464 has now issued as U.S. Patent No. 6,329,159 B1.

Paragraph 6. Rejection of Claims 25-28 and 50-96 Under 35 U.S.C. § 112, Second Paragraph

Claims 25-28 and 50-96 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states the phrase "a cellular response" is ambiguous because the metes and bounds of what is a "response" are not defined and suggests the Applicant amend the claims to recite particular testable cellular responses. In addition, as the claims refer to both "GPR-9-6" and "GPR-9-6 receptor," the Examiner recommends that the Applicant amend the claims to recite one term or the other to maintain consistent terminology throughout the claims. (Office Action at page 2, lines 15-21.)

Claims 25-28 and 50-59 have been canceled, and Claims 60, 73 and 86 have been amended to recite GPR-9-6, thereby obviating the rejection with respect to these claims.

The second paragraph of 35 U.S.C. § 112 requires only that the claims set forth and circumscribe the invention with reasonable degree of particularity and precision. In determining whether particular claims satisfy the requirement of 35 U.S.C. § 112, second paragraph, the claim language must always be analyzed in light of the teaching of the specification and prior art as it would be interpreted by one possessing ordinary skill in the art. In re Moore and Janoski, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). Therefore, a claim is properly rejected under 35 U.S.C. § 112, second paragraph only if it can be concluded that one of ordinary skill in the art, having the Applicant's disclosure before him, would not have a reasonable degree of certainty as to the subject matter encompassed by the claims. Id., at 239.

Claims 60, 73 and 86 have been amended to recite "TECK-induced response." In addition, Applicant's Specification teaches that,

> "As shown herein, TECK is a ligand for GPR-9-6 and activates the receptor leading to TECK-induced Ca^{2+} flux in cells that express GPR-9-6 (Figure 9A). Cells that express mammalian GPR-9-6, including recombinant cells, can also undergo TECK-induced chemotaxis (Figures 8A-8D, 8F, 10, 11A-11B and 13A-13B). Other functions which can be mediated by GPR-9-6 in response to ligand

> binding (e.g., TECK) include, for example, signal transduction (e.g., GDP/GTP exchange by GPR-9-6 associated G proteins, transient increase in the concentration of cytosolic free calcium $[Ca^{2+}]_i$) and GPR-9-6-mediated processes and cellular responses (e.g., proliferation, migration, chemotaxis, secretion, degranulation, inflammatory mediator release (such as release of bioactive lipids such as leukotrienes (e.g., leukotriene C_4)), respiratory burst)."

(Specification at page 14, lines 14-23.)

The specification also includes a detailed discussion of responses mediated by binding of a promoter, such as TECK, to GPR-9-6, and of methods suitable for detecting such responses. (Specification at page 23, line 20 *et seq.*) Further, the specification exemplifies methods for detecting certain TECK-induced responses. (See, *e.g.*, Specification at page 40, line 15 through page 41, line 15, and FIGS. 8A-8D, 8F, 9A, 10, 11A-11B and 13A-13B.)

In view of these extensive teachings and exemplification, and the state of the art of G protein coupled receptors at the time the application was filed, the person of ordinary skill in the art would have no difficulty determining the subject matter of the claims with a reasonable amount of certainty. Therefore, Claims 60, 73 and 86 meet the requirement of 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of the rejection are requested.

Paragraph 7. Rejection of Claims 25-28 and 50-96 Under 35 U.S.C. § 112, First Paragraph

Claims 25-28 and 50-96 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner states that there is not adequate written description in the specification of any essential structural feature common to molecules that are "mammalian GPR-9-6," a "functional variant" of GPR-9-6, a "test agent" or "ligands or promoters" of GPR-9-6. (Office Action at page 3, lines 8-12 and 24-29). The Examiner acknowledges that the application contains adequate written description for a human GPR-9-6 protein of SEQ ID NO:2, a test agent that binds GPR-9-6 that is the chemokine TECK, antibodies which bind the human GPR-9-6 polypeptide of SEQ ID NO:2 and a chemokine ligand of GPR-9-6 that is TECK. (Office Action at page 3, line 30; page 4, line 4 and page 4, line 10.)

The Examiner further states that the claimed method lacks adequate written description because the specification as filed does not describe any essential structural feature common to

molecules that are a "test agent." (Office Action at page 3, lines 26-28.) Applicants respectfully request reconsideration.

Claims 25-28 and 50-59 have been canceled, thereby obviating the rejection with respect to these claims.

The written description requirement of 35 U.S.C. § 112, first paragraph recites that "the specification shall contain a written description of the invention." (35 U.S.C. § 112, first paragraph.) Applicants' invention is a method of detecting or identifying an inhibitor of a mammalian or human GPR-9-6. The detailed teachings and exemplification of the application provide adequate written description of this subject matter. All the components required to practice the claimed methods are sufficiently described in the Specification, as are the methods. For example, Applicants describe a cell expressing a GPR-9-6 receptor with 90% identity to SEQ ID NO: 2 (Specification at page 20, lines 6-10; page 43, line 21- page 44, line 12, page 45 line 12-page 47, line 2; and page 48, Table 1), the ligand TECK (Specification at page 11, lines 2-4 and page 52, lines 9-11), TECK-induced GPR-9-6 responses (e.g., chemotaxis and Ca^{2+} flux) (Specification at page 14, lines 14-23 and at page 26, lines 6-7), and suitable methods for detecting such responses (Specification at page 23, line 20 through page 26, line 29). The particular agent tested is not critical to the method. In fact, Applicants teach that inhibitors can be identified by screening libraries or collections of molecules using the method, and several suitable libraries or collections are identified in the Specification (page 23, lines 3-14). Based on this disclosure, one skilled in the art would conclude that the particular test agent is not critical to the claimed method, and that Applicants were in possession of the method as claimed at the time the application was filed. Reconsideration and withdrawal of the rejection are requested.

Paragraph 8. Rejection of Claims 25-28 and 50-96 Under 35 U.S.C. § 112, First Paragraph

Claims 25-28 and 50-96 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, in that the specification gives insufficient guidance on how to make the test agents. In addition, the Examiner states that the limitless amount of starting material combined with the

lack of guidance as to what particular structure a potential test agent would start out with would lead one of skill in the art with undue experimentation to practice the claimed invention. (Office Action at page 4, lines 29-33.)

The rejected claims are drawn to a method of detecting or identifying an inhibitor of a mammalian or human GPR-9-6. Applicants have adequately described the methods to enable one with skill in the art to practice the claimed methods and to produce the components of the methods, without undue experimentation. For example, the specification contains extensive teachings and exemplification of how to perform binding assays to detect or identify agents that can bind GPR-9-6 or compete with TECK for binding to GPR-9-6 (Specification at page 20, line 19 through page 21, line 11) and functional assays to detect or identify agents that inhibit GPR-9-6 (Specification at page 23, line 20 through page 26, line 29). The application also exemplifies actual reduction to practice of the claimed method (see, for example, Specification at page 47, lines 15-27 and Figures 8B, 8C, 8F and 11A-11C).

Again, the particular test agent is not critical to the claimed method. Nonetheless, suitable methods for making test agents, including libraries or collections of molecules, that could be tested in the method were known in the art at the time the application was filed. Evidence that such methods were known in the art is provided in the specification which cites several references, including three U.S. patents that disclose suitable methods (Specification at page 23, lines 3-18).

In view of the extensive teachings and guidance provided in the application, including the actual reduction to practice of the claimed method, and the state of the art at the time the application was filed, the person skilled in the art could practice the claimed method without undue experimentation. Reconsideration and withdrawal of the rejection are requested.

Paragraph 9. Rejection of Claims 53, 64, 77 and 89 Under 35 U.S.C. § 112, First Paragraph

Claims 53, 64, 77 and 89 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The Examiner states that the MOLT-13 cell line is required to practice the invention and, as a required element, it must be readily available to the public. The Examiner also states

that this requirement would be satisfied by a deposit of the pertinent cell line. (Office Action at page 5, lines 3-11.)

Applicants provide herewith pages from the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) on-line catalog showing that the MOLT-13 cell line is available from this depository. (Reference AS4 in the Supplemental Information Disclosure Statement filed concurrently herewith.) DSMZ is a recognized International Depository Authority under the Budapest Treaty. Withdrawal of the rejection is requested.

Information Disclosure Statement

An Information Disclosure Statement (IDS) with form PTO-1449 (listing references AA, AL, AM, AR-AZ, AR2-AZ2 and AR3-AW3) was filed on September 28, 2001. A Supplemental IDS (SIDS) was filed on April 26, 2002 with form PTO-1449 (listing reference AB), a second SIDS was filed on February 3, 2003 with form PTO-1449 (listing references AX3-AZ3 and AR4), and further SIDSs were filed on July 28, 2003 with form PTO-1449 (listing references AC and AN) and October 14, 2003 with PTO-1449 (listing reference AD). Copies of the forms PTO-1449 filed with the SIDS filed on April 26, 2002 and with the second SIDS filed on February 3, 2003, initialed and dated by the Examiner to indicate that they were considered, were attached to the Office Action.

There is no indication in the Office Action that the other IDSs have been considered by the Examiner. Applicants request that the Examiner acknowledge consideration of each of the IDSs in the next Office Communication, and return initialed and dated copies of the forms PTO-1449 and list of co-pending applications (see SIDS filed on April 26, 2002) to the Applicants.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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